

REMARKS

Claims 6-7, 9-11, and 13-15 are currently pending. Claims 6, 11, and 13 have been amended. The amendments to claims 6, 11, and 13 do not constitute new matter. Claim 14 has been canceled. Upon entry of this amendment, claims 6-7, 9-11, 13, and 15 will be pending.

The Examiner has objected to the specification for failing to include the most recent information regarding the now issued parent application. The Examiner has also objected to the specification for failing to include SEQ ID NOs for all sequences cited in the specification or claims.

The Examiner has rejected claims 6-7, 9-11, and 13-15 under 35 U.S.C. § 112, second paragraph, as allegedly indefinite. The Examiner has rejected claims 6-7, 9, 13, and 15 under 35 U.S.C. § 112, first paragraph, as allegedly lacking support in the written description. The Examiner has rejected claims 6-7, 9, 13, and 15 under 35 U.S.C. § 112, first paragraph, as allegedly lacking enablement. For reasons detailed below, the rejections should be withdrawn and claims allowed to issue. Entry of the foregoing amendments is respectfully requested.

Objections To The Specification

The Examiner has objected to the specification for failing to include the most recent information regarding the parent application. The Examiner has also objected to the specification for failing to include SEQ ID NOs for all sequences cited in the specification or claims. Applicants note that the specification has been amended to cite the patent number of the parent application, as requested by the Examiner. The specification has also been amended to cite SEQ ID NO:1 where appropriate. Accordingly, Applicants submit that the Examiner's objections have been obviated, and respectfully request withdrawal of the objections.

Claims 6-7, 9-11, And 13-15 Are Definite

The Examiner has rejected claims 6-7, 9-11, and 13-15 under 35 U.S.C. § 112, second paragraph, as allegedly indefinite. The Examiner states that the phrase “nucleic acid encoding a poly-beta-hydroxybutyrate biosynthetic pathway” in claims 6 and 7 is unclear because a “poly-beta-hydroxybutyrate biosynthetic pathway” is not a protein, and cannot be encoded by a nucleic acid. The Examiner further asserts that the phrase “which expresses poly-beta-hydroxybutyrate” is unclear because “poly-beta-hydroxybutyrate” is not a protein, and therefore cannot be expressed. The Examiner also states that the phrase “poly-beta-hydroxybutyrate biosynthetic pathway is a 4.826 Kb fragment” in claim 7 is unclear because a “poly-beta-hydroxybutyrate biosynthetic pathway” is not a nucleic acid.

Applicants note that claims 6 has been amended to recite “a nucleic acid encoding the proteins responsible for a poly-beta-hydroxybutyrate biosynthetic pathway.” Support for these amendments can be found in the specification at page 1, line 22 to page 2, line 11. Applicants assert that claims 6 and 7, as amended, are now directed to nucleic acids which encode *proteins*, as opposed to encoding a “biosynthetic pathway.” With regard to the Examiner’s rejection of claim 7 due to the phrase “poly-beta-hydroxybutyrate biosynthetic pathway is a 4.826 Kb fragment,” Applicants submit that the Examiner has read the phrase out of context. The complete phrase is “the nucleic acid encoding the poly-beta-hydroxybutyrate biosynthetic pathway is a 4.826 Kb fragment.” A person of ordinary skill in the art would recognize that the nucleic acid is a 4.826 Kb fragment, not the poly-beta-hydroxybutyrate biosynthesis pathway. As such, Applicants assert that the phrase “the nucleic acid encoding the poly-beta-hydroxybutyrate biosynthetic pathway is a 4.826 Kb fragment” is definite.

The Examiner also states that claims 6-7, 9-11, and 13-15 are unclear because

“the method in the claims fails to recite the substrates used in producing PHBs and steps in contacting the substrate with the enzyme. It is unclear to the Examiner if the substrates are also produced in the transformed microorganism of claim 6 (iii) or if the substrates are present in the medium recited in claim 6 (iv).”

The Examiner asserts that the failure to recite the substrates amounts to the omission of essential elements.

Applicants note that claim 6 has been amended to recite “culturing said *Escherichia coli* JM109 in a conventional medium comprising glycerol and one or more substrates.” Support for this amendment can be found in the specification at page 1, line 22 to page 2, line 11. Applicants submit that the PHB synthetic pathway is well known in the art and well defined in the specification, and therefore the specific substrates and what enzymes they contact need not be recited in the claims. For example, the specification explicitly defines the PHB synthetic pathway, including the enzymes and the substrates involved. See the specification at page 1, line 22 to page 2, line 11. This pathway is well known in the art, and a person of ordinary skill in the art would understand what substrates would be needed to synthesize PHB from the claimed method. Accordingly, a specific recitation of the substrates and which enzymes they contact is not needed, because a person of ordinary skill in the art would be able to understand how the elements of the claim interrelate, and would appreciate the metes and bounds of the claim. See MPEP § 2173.02.

Based upon the foregoing remarks, Applicants submit that the claims are definite, and respectfully request withdrawal of the rejections.

Claims 6-7, 9, 13, and 15 Are Fully Described In The Specification

The Examiner has rejected claims 6-7, 9, 13, and 15 under 35 U.S.C. § 112, first paragraph, as allegedly lacking support in the written description. The Examiner states that while “the claims are drawn to a method of producing PHBs using a genus of polynucleotides having any structure,” there is inadequate support in the specification because it “only teaches one species of a polynucleotide encoding poly-beta-hydroxybutyrate (PHB) synthase.” The Examiner asserts that one species is not sufficient to describe the entire genus, and that the specification fails to describe the relationship between the structure of the disclosed PHB synthase with any recombinants, variants, or mutants.

Applicants note that claim 6 has been amended to recite “isolating a nucleic acid encoding the proteins responsible for a poly-beta-hydroxybutyrate biosynthetic pathway from *Streptomyces aureofaciens* NRRL2209, wherein the nucleic acid comprises SEQ ID NO:1.” Support for this amendment can be found in the specification at page 1, line 22 to page 2, line 11, and at page 8, line 15 to page 9, line 2. This amendment incorporates the limitations of claim 14, and accordingly claim 14 has been canceled. Applicants assert that the claims, as amended, are now directed to nucleic acid encoding proteins for a poly-beta-hydroxybutyrate biosynthetic pathway comprising SEQ ID NO:1, which is amply supported by the specification. *Id.* Accordingly, Applicants assert that the grounds for the Examiner’s written description rejection have been obviated, and respectfully request withdrawal of the rejection.

Claims 6-7, 9, 13, and 15 Are Enabled By The Specification

The Examiner has rejected claims 6-7, 9, 13, and 15 under 35 U.S.C. § 112, first paragraph, as allegedly lacking enablement. The Examiner states that

“[T]he specification, while being enabling for a method of producing PHB using a host cell comprising the polynucleotide having the nucleic acid of SEQ ID NO:1, does not reasonably provide enablement for a method of producing PHB using a host cell comprising any or all variants and mutants of a polynucleotide encoding a *S. aureofaciens* PHB synthase.”

The Examiner asserts that because of this, a person of ordinary skill in the art would not be able to practice the claimed invention.

As noted above, claim 6 has been amended to recite “wherein the nucleic acid comprises SEQ ID NO:1.” Claims 6, 11, and 13 have also been amended to delete reference to “JM109.” Support for these amendments can be found at page 3, line 10 to page 5, line 7. Applicants assert that the claims, as amended, are now directed to a poly-beta-hydroxybutyrate biosynthetic pathway comprising SEQ ID NO:1, which is amply enabled by the specification. See page 1, line 22 to page 2, line 11 and at page 8 line 15 to page 9, line 2. A person of ordinary skill in the art would therefore be able to isolate and utilize the sequence, based upon the teaching of the specification. Furthermore, a person of ordinary skill in the art would be capable of transforming *E. coli* using the identified sequence to generate a transformed *E. coli* capable of producing PHB, based upon the teachings of the specification. Accordingly, Applicants assert that the grounds for the enablement rejection have been obviated, and respectfully request withdrawal of the rejection.

The Examiner has also rejected claims 6-7, 9, 13, and 15 under 35 U.S.C. § 112, first paragraph, as allegedly lacking enablement, for failure to deposit the novel microorganism *E. coli* JM109 PTA 1529. The Examiner has required a declaration by applicant, associated individual or attorney of record, stating that the specific strains of microorganism cited in the claims have been deposited under the Budapest Treaty and that all restrictions imposed by the

depositor on the availability to the public of the deposited material will be irrevocably removed upon grant of a patent, to satisfy the deposit requirements.

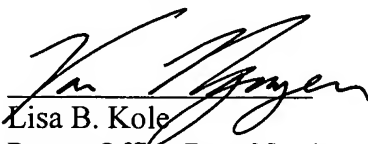
Applicants submit herewith a Declaration of Biological Deposit by the undersigned attorney of record, stating that the specific strains of microorganism cited in the claims have been deposited under the Budapest Treaty. Accompanying the Declaration of Biological Deposit is a Receipt issued by the ATCC, stating that the deposit was made May 28, 2000 and accepted by the International Deposit Authority. Thus, Applicants submit that the deposit requirements have been fulfilled. Since the microorganisms may be made available from the ATCC, the Applicants submit that the specification contains subject matter which describes the invention in a such a way as to enable one of skill in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Based on the foregoing remarks, Applicants assert that the Examiner's grounds of rejection have been obviated, and respectfully request withdrawal of the rejections.

CONCLUSION

Entry of the foregoing amendments and remarks into the file of the above-identified application is respectfully requested. The Applicant believes that the inventions described and defined by claims 6-7, 9-11, 13, and 15 are patentable over the rejections of the Examiner. Withdrawal of all rejections and reconsideration of the amended claims is requested. An early allowance is earnestly sought.

Respectfully submitted,


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